510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a 510k Summary for the use of the Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform.

Submitted By:	Covidien 6135 Gunbarrel Avenue Boulder, CO 80301
Date:	August 16, 2013
Contact Person:	Kelsey Lee Senior Regulatory Affairs Specialist (303) 305-2760
Proprietary Name:	**Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform**
Common Name:	Cardiac Monitor (without alarms)
Device Classification Regulation:	21 CFR 870.2300 – Class II
Device Product Code & Panel:	MWI, OUG
Predicate Device:	**Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform (K130796)**

DEC 04 2013

Device Description
The Vital Sync™ Informatics Manager (IM) & Virtual Patient Monitoring Platform (VPMP) is software that routes parameters, waveforms and alarms from connected devices and displays them on any device that is web-enabled. The Vital Sync™ IM & VPMP can utilize the hospital's network and existing hardware for installation and display or an optional server pre-loaded with the Vital Sync software and off the shelf operating system can be provided. The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform does not alter the parameters, waveforms and alarms displayed and does not control any of the medical devices connected.

This 510k is intended to add new features to the existing Vital Sync IM & VPMP:

Additional User Interface
Additional Report
Auto device Association
Area (zone) Management
Optional Off the Shelf Software/server

Indications for Use/Intended Use
The subject Vital Sync™ IM & VPMP has identical indications for use as the predicate Vital Sync™ IM & VPMP.

The Indications for use are as follows:

The Vital Sync™ Informatics Manager is software that is intended to route and store medical device data and device diagnostic information from supported devices to the Electronic Medical Record (eMR) and Clinical Information System (CIS).

The Vital Sync™ Virtual Patient Monitoring Platform is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the Vital Sync™ Informatics Manager for supported devices. The Vital Sync™ Virtual Patient Monitoring Platform is intended to be used by healthcare professionals for the following purposes:

- To remotely consult regarding a patient's status

- To remotely review other standard or critical near real-time patient data, waveforms and alarms in order to utilize this information to aid in clinical decisions and deliver patient care in a timely manner.

WARNING: The Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform are intended to supplement and not to replace any part of the hospital's device monitoring. Do not rely on the Vital Sync™ Informatics Manager &Virtual Patient Monitoring Platform as the sole source of alarms.

Technological Characteristics Comparison

The subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform and the legally marketed predicate Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform have identical indications for use and both display parameters and waveforms from connected medical devices to a mobile display. Neither the subject nor the predicate can control the connected devices. The subject device is an iteration of the predicate device in that it has additional features: Addition user interface, additional ventilation report, auto-device association, area (zone) management and optional Off the Shelf software/server.

Substantial Equivalence – Non-Clinical Evidence
Safety, efficacy and substantial equivalence was shown through system level verification, user interface verification, system validation, and device compatibility verification. The results of the tests show that the subject Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform can be considered substantially equivalent to the legally marketed predicate.

Substantial Equivalence – Clinical Evidence
N/A – Clinical evidence was not necessary to show substantial equivalence

Substantial Equivalence – Conclusions
Substantial equivalence is shown through systems level testing, user interface testing, and system validation. The subject and predicate device have identical indications for use, similar display features and operating environments. The subject and predicate differ in that the subject device has an additional user interface type, auto device association, zone (area) management, an additional ventilation snapshot and optional Off the Shelf software/server. No new questions of safety and effectiveness have been raised. From the evidence presented in the Premarket Notification, the subject device can be considered substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 4, 2013

COVIDIEN
Kelsey Lee
Sr. Regulatory Affairs Specialist
6135 Gunbarrel Ave, Boulder CO 80301

Re: K132604
Trade/Device Name: Vital Sync Informatics Manager & Virtual Patient Monitoring Platform
Regulation Number: 21 CFR 870.2300
Regulation Name: Cardiac Monitor Without Alarms
Regulatory Class: Class II
Product Code: MWI, OUG
Dated: October 9, 2013
Received: October 10, 2013

Dear Kelsey Lee:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Owen P. Faris -S

for

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Indications for Use

510(k) Number (if known): K132604

Device Name: Vital Sync™ Informatics Manager & Virtual Patient Monitoring Platform

Indications for Use:

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The Vital Sync™ Virtual Patient Monitoring Platform is a remote monitoring platform that displays physiologic data, waveforms and alarms routed through the Vital Sync™ Informatics Manager for supported devices. The Vital Sync™ Virtual Patient Monitoring Platform is intended to be used by healthcare professionals for the following purposes:

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Prescription Use ___X___ AND/OR Over-The-Counter Use_____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED)

CONCURRENCE OF CDRH, OFFICE OF DEVICE EVALUATION (ODE)

Digitally signed by Owen P.
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